IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 5 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF BRUCE ROSENZWEIG, M.D.

Defendants Ethicon, Inc., Ethicon LLC, and Johnson & Johnson (hereinafter "Ethicon") submit this memorandum in support of their motion to exclude certain opinions of Bruce Rosenzweig, M.D., with respect to the cases set forth in Exhibit A.

Ethicon's brief in this wave of cases is very similar to its brief submitted for the Wave 3 cases, and Ethicon has incorporated herein by reference several aspects of that brief. As set forth herein, Ethicon presents the following arguments that have not previously been argued and/or that have been supplemented with additional authorities: (a) in Section I, Ethicon requests that the Court preclude Plaintiffs from incorporating by reference multiple expert reports of Dr. Rosenzweig relating to the same device; (b) in Section II, Ethicon requests that the Court preclude Dr. Rosenzweig from comparing Ethicon's devices with traditional surgical procedures consistent with recent rulings by this Court and others; (c) in Section VII, this brief highlights a *Daubert* ruling by the United States District for the Northern District of Illinois as it relates to a Wave 1 case remanded from this Court (*see Walker v. Ethicon, Inc.*, 2017 WL 2992301 (N.D. Ill. June 22, 2017)), and (d) in Section XI, Ethicon requests that the Court preclude Dr. Rosenzweig

from providing opinions about the Prolift device, because he has not disclosed any opinions about that device.

INTRODUCTION

Dr. Rosenzweig is a pelvic surgeon and urogynecologist with experience in the surgical treatment of stress urinary incontinence ("SUI") and pelvic organ prolapse, as well as the removal of sling systems. Ex. B, curriculum vitae. He intends to provide general opinions about TVT, TVT-O, TVT-Abbrevo, TVT Exact and TVT Secur (collectively "the TVT Devices"), which are used for the surgical treatment of SUI, as well as general opinions about Prosima, which is used for the surgical treatment of prolapse. Ex. C-H, Expert Reports.[1] As set forth below, the Court should preclude Dr. Rosenzweig from testifying about matters that are beyond his expertise, that are irrelevant, that are unreliable, that are prejudicial, and/or that would confuse or mislead the jury.

LEGAL ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions set forth by the Court in *Huskey v. Ethicon, Inc*., 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014).

I. Plaintiffs' broad and vague attempts to rely on unspecified prior reports of Dr. Rosenzweig is improper.

Under PTO No. 248, Plaintiffs had a May 22, 2017 deadline to submit their expert disclosures. The Plaintiffs set forth in Exhibit A have disclosed their intent to rely on Dr. Rosenzweig, who prepared a general Wave 5 general report for six different devices. Five of Dr. Rosenzweig's Wave 5 reports broadly state that "I incorporate my past reports and testimony" about each device. Ex. C, TVT-O Report at 116; Ex. D, TVT Report at 99; Ex. E, TVT-S Report

[1] As set forth in Section I below, Plaintiffs have purported to rely on multiple reports from Dr. Rosenzweig, particularly as they relate to the TVT and TVT-O devices. Ethicon, however, has only filed those reports that Dr. Rosenzweig has submitted specific to this Wave 5 of cases.

at 83; Ex. F, TVT Abbrevo Report at 71; Ex. H, TVT Exact Report at 68. Further, several of Plaintiffs' expert designations broadly purport to reference all of Dr. Rosenzweig's past reports without specifying which report. *See, e.g.,* Ex. I, Dobard Expert Designation at 2; Ex. J, Leith Expert Designation at 1. To make matters worse, Plaintiffs have filed a "Notice of Adoption of Prior Expert Reports and Testimony of Dr. Bruce Rosenzweig" purporting to adopt six different previous reports submitted by Dr. Rosenzweig with respect to the TVT and TVT-O devices "to be used at the discretion of the individual plaintiffs in the cases designated in Wave 5, and any future waves of Ethicon cases designated by the Court." Doc. 3947. Ethicon has filed a motion to strike that notice, to which Plaintiffs never responded, and that motion is pending. *See* Doc. 4045.

Dr. Rosenzweig does not identify or limit the "past reports" that he intends to incorporate by reference. Ex. C, TVT-O Report at 116; Ex. D, TVT Report at 99; Ex. E, TVT-S Report at 83; Ex. F, TVT Abbrevo Report at 71; Ex. H, TVT Exact Report at 68. At this point in this litigation, many experts, including Dr. Rosenzweig, have submitted a multitude of reports—both general and case-specific. Vague and expansive references to any and all other reports that may have submitted throughout the course of this litigation could lead to uncertainty and confusion about what opinions a particular expert intends to provide at trial. Thus, Ethicon requests that Dr. Rosenzweig rely on only one report per device for this wave of cases and future waves of cases.

II. The Court should preclude Dr. Rosenzweig from testifying that non-synthetic mesh procedures are a safer alternative.

Dr. Rosenzweig believes that "traditional surgeries like the Burch and pubovaginal slings" lead to fewer complications than TVT Devices for the surgical treatment of SUI, and that traditional native tissue repairs are a safer alternative to Prosima for the surgical treatment of

pelvic organ prolapse. *See* Ex. C, TVT-O Report at 108-109; Ex. D, TVT Report at 93; Ex. E, TVT-S Report at 75; Ex. F, TVT Abbrevo Report at 67; Ex. H, TVT Exact Report at 66; Ex. G, Prosima Report at 45. Any alleged comparative benefits of the traditional approaches to treat SUI and prolapse recommended by Dr. Rosenzweig are not even relevant to Plaintiffs' design defect claims, because these approaches are not even a medical device and do not entail altering the design of the devices. Ethicon challenged these opinions in its Wave 1 briefing, and the Court determined that "[t]he relevance of this expert testimony is better decided on a case-by-case basis," and therefore, reserved ruling. *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4500765, at *3 (S.D.W. Va. Aug. 26, 2016). Since that time, however, the Court has issued several rulings suggesting that this should be revisited.

First, the Court has determined that opinions about alternative procedures are not a case-specific issue, but instead, an issue within "the province of a general causation expert—not a specific causation expert." *Brooks v. Ethicon, Inc.*, No. 2:12-cv-02865, Mem. Op. at 4 (S.D.W. Va. July 12, 2017), Ex. K hereto.

Second, this Court recently precluded one of Plaintiffs' other general causation experts, Dr. Nathan Goodyear, from offering very similar opinions. In *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2017 WL 1264620, at *3 (S.D.W. Va. Mar. 29, 2017), the Court stated:

> Ethicon argues that Dr. Goodyear's opinions regarding *alternative procedures* are irrelevant to the question of whether a safer alternative design of a product exists. Ethicon states, "[A] medical device *product is* not defective in design simply because alternative surgical and nonsurgical *procedures* may exist." Defs.' Mem. Supp. Mot. 4. ***I agree with Ethicon that alternative procedures/ surgeries do not inform the issue of whether an alternative design for a product exists.*** Accordingly, Ethicon's Motion on this point is **GRANTED** and Dr. Goodyear's alternative procedures testimony is **EXCLUDED**.

(Emphasis added).

Third, in *Mullins v. Johnson & Johnson*, 2017 WL 711766, at *2 (S.D.W. Va. Feb. 23, 2017), the Court explicitly found that "[e]vidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT." The Court reasoned that "other surgeries or procedures do not inform the jury on *how* the TVT's design could have feasibly been made safer to eliminate the risks that caused the plaintiffs' injuries." *Id.* (emphasis in original). The Court further found that the "the plaintiffs must provide evidence of an alternative, feasible design for the *product* at issue," which entails "provid[ing] sufficient evidence to identify a comparable product or design concept, whether the *design features* of the comparable product or the *design concept* existing at the time of the [device's] manufacture . . . ." *Id.* at *3 (emphasis in original). *See also Schmidt v. C.R. Bard, Inc.*, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013) ("[N]on-mesh repair is not an alternative design and does not meet Plaintiff's burden to support" a design-defect claim).[2]

Relying on this reasoning, an Illinois federal district court recently precluded another plaintiffs' expert, Dr. Bobby Shull, from testifying that traditional procedures are safer alternatives to the Prolift +M device, stating "[t]he Court agrees with the MDL Court and Defendants that evidence regarding a different surgical procedure not involving mesh is irrelevant to the existence of a safe alternative design for the product at issue in this case." *Walker v. Ethicon, Inc.*, 2017 WL 2992301, at *2 (N.D. Ill. June 22, 2017). The court held as such even though the Illinois law applied in that case did not require the plaintiff to prove the existence of a safer alternative. *See Dunning v. Dynegy Midwest Gen., Inc.*, 2015 IL App. (5th) 140168, ¶66, 33 N.E.3d 179, 197-98 (2015).

[2] These rulings are in accord with others. *See, e.g., Linsley v. C.R. Bard, Inc.*, 2000 WL 343358, *3 (E.D. La. Mar. 30, 2000) (holding that while there existed "alternative techniques" for the mesh surgery, such techniques did not prove an "alternative design" for the polypropylene surgical mesh product). They reflect a general principle of product liability law that applies whenever a safer alternative design is claimed.

The notion that traditional surgical procedures are safer alternatives to Ethicon's devices "really takes issue with the choice of treatment made by [the patient]'s physician, not with a specific fault of" the medical device. *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th. Cir. 1999). Thus, Dr. Rosenzweig's opinions about these traditional surgical procedures are not changes to the design feature or the design concept of the device at issue; instead, his opinions would eliminate the device in its entirety. *See also Nease v. Ford Motor Co.*, 848 F.3d 219, 234 (4th Cir. 2017) (finding that controlling case law may "only be read to require the production of evidence on reasonable alternative design, to gauge what 'should have been'") (quoting Restatement (Third) of Torts: Products Liability § 2, Reporter's Note (1998)).

Plaintiffs really takes issue with their implanting physicians' choice to recommend a medical device (ie. TVT or Prosima) rather than another form of non-device surgery (ie. Burch or colporrhaphy). But that choice depends on a number of factors beyond Ethicon's control, including the experience and training of the physician, which is why the law trusts the physician with that decision and does not make the decision for him by allowing a jury to substitute its judgment. Dr. Rosenzweig's testimony about any alleged comparative benefits of these alternative surgical alternatives to the TVT Devices or Prosima is irrelevant and inadmissible.[3]

III. The Court should preclude Dr. Rosenzweig from testifying that devices with a different type of mesh are safer alternatives for the surgical treatment of SUI or prolapse.

Ethicon adopts its Wave 3 argument on this issue set forth in Section I of Doc. 2818.

[3] In fact, Dr. Rosenzweig's opinions would be irrelevant and inadmissible if he compared the devices with another medical device that has its own unique advantages and disadvantages to be weighed by the surgeon. *See, e.g., Talley v. Danek Med., Inc.*, 179 F.3d 154, 162 (4th Cir. 1999) (rejecting plaintiff's theory that defendant's spinal-fixation screws were defective because there were alternative spinal-fusion procedures using a different device, ie. wires and hooks).

IV. The Court should preclude Dr. Rosenzweig from criticizing the cut of TVT mesh.

Ethicon adopts its Wave 3 argument on this issue set forth in Section II of Doc. 2818.

V. The Court should limit Dr. Rosenzweig's product warning opinions.

Ethicon adopts its Wave 3 argument on this issue set forth in Section III of Doc. 2818.

VI. The Court should preclude Dr. Rosenzweig from testifying about alleged mesh degradation and other biomaterials opinions.

Ethicon adopts its Wave 3 argument on this issue set forth in Section IV of Doc. 2818.

VII. The Court should preclude Dr. Rosenzweig from testifying about duties allegedly owed by a manufacturer.

Dr. Rosenzweig asserts a number of opinions about duties allegedly owed by Ethicon as a medical device manufacturer that are well outside of Dr. Rosenzweig's expertise. Dr. Rosenzweig is not qualified to provide such testimony, and his opinions are unreliable.

A. Testing

Dr. Rosenzweig suggests that Ethicon did not perform adequate testing and studies. *See, e.g.*, Ex. C, TVT-O Report at 11-20, 106-108; Ex. D, TVT Report at 12-13, 19, 63-65; Ex. E, TVT-S Report at 20-21, 74-75; Ex. F, TVT Abbrevo Report at 20-21, 65; Ex. H, TVT Exact Report at 19-20, 64-65; Ex. G, Prosima Report, pp. 19-20, 42-47. In fact, the TVT is one of the most-tested medical devices ever made. In precluding Dr. Rosenzweig from offering similar testimony, this Court found that "[t]here is no indication that Dr. Rosenzweig has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake." *In re: Ethicon,* 2016 WL 4500765, at *5; *Huskey*, 29 F. Supp. 3d at 705. Dr. Rosenzweig has gained no additional expertise, and accordingly, the same reasoning continues to apply.

B. Adverse Event Reporting

For similar reasons, this Court also should exclude Dr. Rosenzweig's opinion that "Ethicon's collection and reporting of adverse events and complications to physicians and patients was incomplete, inaccurate and misleading." Ex. C, TVT-O Report at 100-101; Ex. E, TVT-S Report at 69; Ex. F, TVT Abbrevo Report at 59; Ex. H, TVT Exact Report at 58-59. Dr. Rosenzweig's experience as a surgeon does not qualify him to render opinions on adverse event reporting. He has no relevant experience with the FDA or in the medical device industry that would permit him to offer expert testimony regarding the standard of care for collecting and reporting adverse events. *See, e.g., In re Diet Drugs*, MDL No. 1203, 2001 WL 454586, *16 (E.D. Pa. Feb. 1, 2001) (excluding heart surgeon's opinions regarding adverse event reporting because surgeon had "no experience or expertise in . . . adverse event reporting" and based his opinions on personal belief rather than reliable methodology).

Not surprisingly, because Dr. Rosenzweig has no relevant experience, he is unable to identify a single rule or regulation that would require Ethicon to collect and report adverse events in the manner he suggests it should have. In fact, Dr. Rosenzweig does not identify *any* basis or reason for his opinion, as he must. Instead, his opinion is apparently based purely on personal belief. The Court should exclude his opinion on that basis. *See Hines v. Wyeth*, 2011 WL 2680842, *5 (S.D. W. Va. July 8, 2011) (finding that expert provided no basis for opinions, rendering them inadmissible "personal opinion").

Dr. Rosenzweig's critique of Ethicon's adverse event reporting amounts to nothing more than a narrative summary of the evidence. Dr. Rosenzweig cites or quotes Ethicon e-mails and company witness depositions purporting to show that Ethicon employees did not know how many complaints were missed by the company's "complaint tracking system." Because the jury does not need an expert witness to read documents and summarize evidence, the Court should exclude Dr.

Rosenzweig's opinions regarding adverse event reporting. *See, e.g.*, *Hines*, 2011 WL 2680842, at *7 (excluding as "irrelevant" and "unhelpful" expert opinion "based on [the expert's] own reading of defendants' internal documents" that the "jury is more than capable of reading and summarizing"); *In re: Ethicon,* 2016 WL 4500765, at *7 ("caution[ing] the parties against introducing corporate evidence through expert witnesses").

In its Wave 1 ruling, this Court found that "opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED.**" *In re: Ethicon, Inc.*, 2016 WL 4500765, at *6. The Court should do so again here and clarify that all of Dr. Rosenzweig's adverse event reporting opinions are excluded, regardless of whether they are specific to compliance with FDA regulations. In *Walker v. Ethicon, Inc.*, 2017 WL 2992301 (N.D. Ill. June 22, 2017), the Illinois federal district court prevented Dr. Shull from providing similar criticisms of Ethicon's response to adverse event reports. *Id.* at *6. According to the court, "[s]imilar to the MDL Court excluding Dr. Shull's opinion regarding product testing or clinical trials in another case based on a lack of experience with such matters, *see Carlson*, 2015 WL 1931311, at *15, the Court excludes Dr. Shull's opinion regarding the standard of care for adverse event reporting because Plaintiffs have not demonstrated that Dr. Shull has relevant experience to testify as an expert about this matter." *Id.* The court further "note[d] that Dr. Shull cannot serve as a conduit for corporate information by testifying about the extent of Defendants' adverse event reporting." *Id.*

C. Training

Dr. Rosenzweig claims that Ethicon did not fund and provide appropriate training to physicians concerning the use of TVT-O and TVT-S. Ex. C, TVT-O Report at 77-79; Ex. E, TVT-S Report at 78-82. Dr. Rosenzweig is not qualified to testify about what funding and level of training that a medical device manufacturer should provide. Further, his opinions are based on a narrative

summary of documents rather than any special expertise. In addition, Dr. Rosenzweig's opinions are irrelevant and prejudicial insofar as he does not claim that a specific Plaintiff's implanting physician was not appropriately trained or competent. *See Cisson*, 948 F. Supp. 2d at 614 (excluding similar opinions about training under similar circumstances). Consistent with the Illinois federal court's ruling in *Walker, supra*, the Court should determine that any of Dr. Elliott's opinions about training should be limited to a discussion of "the risks of implanting mesh and whether Defendants' product materials raise those risks, but he may not offer testimony about 'what information should or should not be included in an [Instructions for Use]' or other similar materials." *Walker*, 2017 WL 2992301, at *6.

VIII. The Court should preclude Dr. Rosenzweig from testifying about certain alleged complications associated with TVT-Abbrevo.

Ethicon adopts its Wave 3 argument on this issue set forth in Section VI of Doc. 2818.

IX. The Court should exclude Dr. Rosenzweig's marketing opinions.

Ethicon adopts its Wave 3 argument on this issue set forth in Section VII of Doc. 2818.

X. The Court should preclude Dr. Rosenzweig from testifying about MSDS sheets.

Ethicon adopts its Wave 3 argument on this issue set forth in Section VIII of Doc. 2818.

XI. The Court should prevent Dr. Rosenzweig from providing general opinions about Prolift.

Dr. Rosenzweig has prepared general reports in this and other waves of cases only for certain devices, but he has not prepared a report for Prolift. Although several Plaintiffs set forth in Exhibit A to Defendants' motion—Plaintiffs Blake, Clark, Dobard, Frame, Fremin, Heintz, Holley, Leith, Nethercott, and Sciumbata—were implanted with Prolift and designated Dr. Rosenzweig to provide general causation opinions, Dr. Rosenzweig has not disclosed any opinions with respect to that device. *See* Case No. 2:12-cv-07901, Doc. 1, ¶8; Case No. 2:12-cv-06481, Doc. 1, ¶8; Case No. 2:12-cv- 07493, Doc. 1, ¶8; Case No. 2:12-cv- 07524, Doc. 1, ¶8;

Case No. 2:12-cv- 07523, Doc. 1, ¶8; Case No. 2:12-cv- 07579, Doc. 1, ¶8; Case No. 2:12-cv-07750, Doc. 1, ¶8; Case No. 2:12-cv-08079, Doc. 1, ¶8; Case No. 2:12-cv- 05802, Doc. 1, ¶8; Case No. 2:12-cv- 07037, Doc. 1, ¶8. Collective Ex. L, Expert Designations in those cases.[4] Because Plaintiffs have not disclosed any opinions of Dr. Rosenzweig related to Prolift, they should not be allowed to elicit opinions from him about that product. *See* Fed. R. Civ. P. 26(a)(2)(B)(i); *Lewis v. Ethicon, Inc.,* 2014 WL 186872, at *17 (S.D. W. Va. Jan 15, 2015) ("Under Rule 26, expert reports must contain 'a complete statement of all opinions the witness will express and the basis and reasons for them'"). Otherwise, Ethicon would be prejudiced.

XII. The Court should not allow other opinions that are beyond Dr. Rosenzweig's expertise and/or otherwise improper.

Ethicon adopts its Wave 3 argument on this issue set forth in Section IX of Doc. 2818.

CONCLUSION

For the reasons set forth and referenced herein, Defendants respectfully request that the Court grant their Motion to Exclude the Testimony of Bruce Rosenzweig, M.D.

[4] Certain of these Plaintiffs were also implanted with another device for which Dr. Rosenzweig has submitted a report. Therefore, those Plaintiffs may only have intended to designate Dr. Rosenzweig to testify about another device, although their designations are unclear. In any event, those Plaintiffs should only be allowed to elicit testimony from Dr. Rosenzweig with respect to a device in which they have been implanted and he has disclosed an expert report.

Respectfully Submitted,

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I hereby certify that on this day I electronically filed the foregoing document with the Clerk of the Court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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